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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE CONNETICS CORP. SECURITIES LITIGATION

Case No. C 07-02940 SI

REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT BY DEFENDANTS CONNETICS CORP., JOHN L. HIGGINS, LINCOLN KROCHMAL, C. GREGORY VONTZ, AND THOMAS G. WIGGANS

Date: August 15, 2008
Time: 9:00 a.m.
Dept: Courtroom 10
Judge: Honorable Susan Illston

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STATUTES

I. INTRODUCTION

Plaintiff's opposition abandons the theory of liability set forth in its earlier complaint and advanced during the previous proceedings before this Court. In its prior complaint and papers, plaintiff contended that defendants knew Velac could never be approved by the FDA because of the Tg.AC test results. Now, plaintiff acknowledges that the Tg.AC test results were inconclusive and that the FDA could approve Velac despite those results, but nonetheless argues that defendants misled investors about the timing of approval. To support its new "timing" theory, plaintiff repeatedly argues that defendants knew as early as June 2004 that Velac could not be approved by the date set by the FDA – the so-called PDUFA date – because Connetics had to conduct "additional testing to demonstrate that Velac was not a carcinogen." Opp. at 15.

Although signaling a significant retreat, plaintiff's opposition nonetheless fails to cite any factual support for its new theory, much less address the pleading deficiencies identified by this Court. Plaintiff simply has no answer for the fact that the ***FDA never said*** at any point during the approval process – not during the pre-NDA meeting, not in the 74-day letter, not during any of its frequent communications with Connetics, not during the alleged April 13, 2005 phone call with ECAC – that Velac required additional testing. Plaintiff also has no meaningful response to the fact that the FDA had approved other acne drugs that had proved to be "tumor promoters" in Tg.AC studies, subject only to ***post-approval*** Phase IV carcinogenicity testing and labeling requirements. The approval of those drugs refutes any inference that the "FDA would not approve a drug that tested positively in a Tg.AC study without first obtaining the results of additional testing" – much less that defendants actually believed that to be the case. Opp. at 13.

Instead of setting forth facts in support of its new theory, plaintiff impermissibly attempts to evade its pleading burden. To that end, plaintiff repeatedly argues that defendants "proffer no evidence . . ." (Opp. at 23), "offer no basis to believe . . ." (*id.* at 28), and fail to identify the "percentage of drugs that test positive and the FDA rejects" (*id.* at 23). However, the Reform Act and *Tellabs* are clear that plaintiff bears the burden of pleading particularized facts creating the necessary cogent and compelling inference of scienter. Plaintiff cannot shift the burden to defendants. Indeed, despite defendants' challenge to do so, plaintiff has not identified ***a single***

drug prior to Velac that was denied approval because of a positive response in a Tg.AC study, much less one that was brought to defendants' attention.

Plaintiff also cannot reconcile its new "timing" theory with defendants' concrete business decisions. The facts are undisputed that Connetics filed the Velac NDA in August 2004 and thereby triggered a $3.5 million milestone payment to Yamanouchi Europe B.V., Velac's licensor. If defendants knew that the Velac NDA was deficient and that Velac required additional pre-approval carcinogenicity testing as early as June 2004, as plaintiff claims, then why would defendants submit a knowingly deficient NDA and incur all of the expense associated with the submission, instead of simply performing the additional testing? Likewise, why would defendants incur yet even more expense to ready Connetics' sales force and to prepare for the launch of Velac if they knew that the Velac NDA was deficient? Plaintiff has no meaningful explanation. The only reasonable inference to draw from defendants' actual decisions is that defendants believed that Velac would be approved by the PDUFA date.

Plaintiff's failure to plead particularized facts creating the necessary cogent and compelling inference of scienter is fatal to every Velac-related claim, not just the claims based on forward-looking statements. Indeed, plaintiff cannot cite a single case or principle supporting its illogical argument that the Court can credit all of the reasons defendants had to believe in Velac when addressing forward-looking statements, but then ignore those very same reasons when addressing other statements. Opp. at 19. Plaintiff fares no better by citing alleged statements by so-called anonymous "witnesses" because ***nobody*** claims to have told defendants that the Velac NDA was deficient or that Velac required additional testing. In any event, the alleged concerns raised by the unnamed "sources" are devoid of the factual detail required by the Reform Act, and as this Court has already recognized, defendants could reasonably disagree with such concerns because of the many positive facts supporting the Velac NDA.[1]

Finally, this Court previously ruled that plaintiff had failed to plead facts showing that Connetics' modest restatement was the product of fraud rather than an innocent or even negligent

[1] Order Granting Defendants' Motion to Dismiss and Defendants' Motion to Strike, Jan. 19, 2008 ("Order") at 14.

mistake. Order at 18-20. Plaintiff's opposition, like the SAC, does not identify any new facts to bolster its claim. Instead, plaintiff offers a variety of old and new arguments as to why such detail need not be provided – notwithstanding this Court's prior ruling, the Reform Act, and controlling law. None of these arguments has merit.

II. PLAINTIFF'S OPPOSITION FAILS TO CURE THE FUNDAMENTAL DEFECTS IN ITS VELAC-RELATED CLAIMS

A. Plaintiff Cannot State A Claim With Respect To Forward-Looking Statements

1. Plaintiff Cannot Plead Actual Knowledge of Falsity

Plaintiff's opposition does nothing to address this Court's holding that plaintiff cannot establish a "strong inference that defendants had actual knowledge of falsity at the time their predictions about Velac were made because during this period defendants had not heard anything from the FDA indicating that the FDA had concerns about the results of the transgenic mouse test." Order at 14; *see also Constr. Laborers Pension Trust v. Neurocrine Biosciences, Inc.*, 2008 WL 2053733, at *5 (S.D. Cal. May 13, 2008) (dismissing claim where plaintiff did not allege FDA expressed concerns about approvability of drug at time of optimistic statements regarding approval). Plaintiff's opposition also does nothing to address the fact that nobody – not CW 5, not CW 6, and not the expert panel – ever told any of the defendants that Velac required additional carcinogenicity testing before it would be approved by the FDA. SAC ¶¶ 43(e), 43(f), 94. Finally, plaintiff says nothing about this Court's holding that defendants could be optimistic about Velac's prospects for approval irrespective of any "concerns expressed by their panel of experts." Order at 14. As this Court recognized, defendants could reasonably disagree with any such concerns, particularly because the FDA had not expressed such concerns and defendants were aware of other drugs that had been approved despite a positive Tg.AC test result. *Id.*

Faced with this Court's prior holding and the FDA's approval of other dermatological drugs that tested positive in animal carcinogenicity tests, plaintiff resorts to a number of fruitless arguments. *First*, plaintiff argues that defendants' citation to those drugs is "procedurally improper." Opp. at 13. However, this Court has held that it must take judicial notice of the regulatory approval of other drugs when determining whether plaintiff has met its burden of

pleading a cogent and compelling inference of scienter. Order at 14. n.5 (citing *In re CV Therapeutics, Inc. Sec. Litig.*, 2004 WL 1753251, at *4 (N.D. Cal. Aug. 5, 2004)); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007) (holding that court "must consider" matters subject to judicial notice); *In re Vertex Pharms. Inc. Sec. Litig.*, 357 F. Supp. 2d 343, 352 (D. Mass. 2005) (taking judicial notice of FDA approval of drug).

Second, plaintiff mischaracterizes the FDA's approval of BenzaClin and Duac by arguing that the post-approval testing required by the FDA related to "the effects of the drug on UV-induced skin cancers." Opp. at 13. In fact, the FDA approved BenzaClin and Duac subject to ***both*** post-approval dermal carcinogenicity testing ***and*** post-approval UV-induced skin carcinogenicity testing. The approval letter for BenzaClin states:

> You have agreed to submit the following protocols within 9 months of the approval of this application: . . . To conduct a ***dermal carcinogenicity study*** and a study on the effects of UV-induced skin carcinogenicity. These studies should be completed and submitted within 4 years of the approval of this application.

Ex. 31, at 2 (emphasis added).[2] Similarly, the approval letter for Duac states:

> We remind you of your post marketing study commitments . . . .
>
> 1. The Applicant commits to performing ***dermal carcinogenicity testing*** of the combination drug product. . . . .
>
> 2. The Applicant commits to a study to evaluate the effects of the drug products on UV-induced skin cancers. . . .

Ex. 33, at 1-2 (emphasis added). The approval letters are clear that both drugs were approved even though the drugs tested positive in Tg.AC mice and the applicants had not yet conducted additional animal carcinogenicity testing.

Third, plaintiff wrongly speculates that the FDA may have required the BenzaClin and Duac applicants to conduct "additional ***pre-approval*** carcinogenicity testing demonstrating that the drug[s] [were] not a carcinogen" before issuing the approval letters. Opp. at 13 (emphasis in original). Plaintiff's argument is inherently illogical. If the applicants had demonstrated that

[2] Unless otherwise noted, all references to exhibits are to those attached to the Steskal Declaration and will appear in the form "Ex.__."

BenzaClin and Duac were not carcinogenic prior to approval, there would be no need for post-approval carcinogenicity testing. Moreover, plaintiff pleads no facts to support its argument, much less facts indicating that defendants had "actual knowledge" that the FDA required those drug applicants to demonstrate that a product was not a carcinogen prior to approval.

Fourth, plaintiff also wrongly argues that defendants' citation to drugs such as BenzaClin and Duac is "contrary to Defendants' own Class Period statements" and "appears to be *post hoc* reasoning solely for litigation." Opp. at 13. Nothing could be further from the truth. For example, during an April 26, 2005 analyst call, Mr. Wiggans noted, among other things, that "benzoyl peroxide, a commonly used OTC [over the counter] acne product, an ingredient in several prescription acne products, has Rx labeling that notes a positive result in this model." SAC ¶ 263. More importantly, the fact that the FDA ***had approved*** such drugs subject to post-approval testing eviscerates plaintiff's assertion that Velac could not be approved without future pre-approval testing, and guts its theme that defendants had "actual knowledge" that this could "never" occur.[3]

Finally, plaintiff's opposition misstates the law. Courts have repeatedly recognized that potential problems arise routinely in the course of seeking approval of a new drug and that defendants were entitled to remain optimistic that any such problems could be overcome. *See In re Syntex Corp. Sec. Litig.*, 95 F.3d 922, 930 (9th Cir. 1996) ("company could have known of problems in the testing procedures, planned to remedy those deficiencies, and still thought it would achieve FDA approval by the estimated date").[4] The few cases cited by plaintiff do not

[3] Moreover, because plaintiff alleges fraud on the market, the law requires a court to consider all judicially noticeable facts that were available to the market – including regulatory actions by the FDA – when deciding whether plaintiff has pleaded a strong inference of scienter. *Tellabs*, 127 S. Ct. at 2509; *see also* Reply RJN at 6-12.

[4] *See also Ronconi v. Larkin*, 253 F.3d 423, 434 (9th Cir. 2001) ("Problems and difficulties are the daily work of business people. That they exist does not make a lie out of any of the alleged false statements"); *Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 53 (2d Cir. 1995) (holding that disclosure of FDA inspection deficiencies was not required where "one cannot infer that it was a 'foregone conclusion'" that the plant would fail the inspection and the FDA would close the plant); *In re CBT Group PLC Sec. Litig.*, 1999 WL 1249287, at *3 (N.D. Cal. July 21, 1999) (even "if a company knows that a problem exists, it could still honestly and in good faith report that the company will continue to perform as expected"); *Vertex Pharms.*, 357 F. Supp. 2d at 352 (undisclosed preclinical animal tests that signal toxicity do not render optimistic statements about Phase I and II human clinical trials knowingly false or misleading); *Noble Asset Mgmt. v. Allos*

hold otherwise. In *Warshaw v. Xoma Corp.*, 74 F.3d 955 (9th Cir. 1996), for example, the Ninth Circuit applied the pre-Reform Act pleading standard and held that plaintiff adequately alleged a claim where the facts showed that the FDA and an analyst told defendants that their Phase III clinical tests were inadequate and approval was unlikely, but defendants nonetheless told the market that approval was "imminent." Unlike in *Xoma*, and as this Court has already recognized, the FDA never told defendants that Velac required additional testing, and defendants had multiple reasons to be optimistic about Velac's prospects for approval by the PDUFA date. *See Syntex*, 95 F.3d at 930 (distinguishing *Xoma* based on its facts); *Neurocrine Biosciences*, 2008 WL 2053733, at *5 (holding that *Xoma* did not apply where facts showed that FDA did not make negative comments about drug candidate at time allegedly false statements were made).[5]

2. Plaintiff Cannot Evade The Safe Harbor

Plaintiff incorrectly argues that this Court has already held that the safe harbor does not apply to the forward-looking statements at issue. Opp. at 16. In fact, this Court has not yet addressed the application of the safe harbor to plaintiff's significantly narrowed "timing" theory of liability. Connetics' cautionary statements were more than sufficient to warn investors that the timing of approval was uncertain and that its revenue projections would be adversely affected by

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Therapeutics, Inc., 2005 WL 4161977, at *7 (D. Colo. Oct. 20, 2005) ("fact that the FDA staff members raised questions did not impose a duty upon the defendants to revise their opinions about the drug's efficacy or to report to the public the substance of their conversations with the FDA"); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1224-25 (S.D. Cal. 2001) (undisclosed statements by FDA advisory committee about product's toxicity did not foreclose possibility of FDA approval); *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995) ("Mere questioning by the FDA imposed no duty upon Defendants either to trim back their opinions as to the efficacy of the drug or to report to the public the FDA staffers' questions as they arose.").

[5] In addition, although plaintiff asserts that cases such as *MedImmune* are contrary to the "great weight of authority" (Opp. at 20-21), the only case plaintiff cites says no such thing. In *In re Amylin Pharms. Inc. Sec. Litig.*, 2003 WL 21500525 (S.D. Cal. May 1, 2003), the court held that plaintiff adequately alleged falsity where defendants represented that a drug's clinical trial results "met the requirements for FDA approval," but did not disclose that the FDA had already told defendants that its clinical trial results were not sufficient to gain approval. *Id.* at *8. The *Amylin* court accepted *MedImmune*'s holding that a defendant's optimistic statements regarding a drug are not false merely because the FDA raises concerns about the drug. *Id.* In each of the other cases cited by plaintiff elsewhere, the gravamen of the claim was that defendants made "allegedly fraudulent and/or misleading statements of historical fact." *CV Therapeutics*, 2004 WL 1753251, at *10 (defendants made misleading statements contrary to known facts, such as the FDA's stated reasons for cancellation of a meeting with defendants and the contents of FDA correspondence).

any delay.[6] *See* Def. Mem. at 19-20; s*ee also Neurocrine Biosciences*, 2008 WL 2053733, at *10 (applying safe harbor to statements regarding new drug candidate where "warnings explained the precise risk which materialized when the FDA found the [NDA] insufficient"). Indeed, the Ninth Circuit has recognized that even in the absence of cautionary statements, investors understand that any prediction regarding the timing of FDA approval is inherently uncertain. *Syntex*, 95 F.3d at 930 ("Clearly, Defendants' prediction of a date for a regulatory decision over which they did not have control, made that far in advance, for a drug that was still in the testing stages, could not carry a guarantee of accuracy or reliability.").

Plaintiff cannot circumvent the safe harbor by arguing that the projections at issue are not forward-looking because defendants allegedly failed to disclose "historical facts." Opp. at 16-17. It is the nature of the statement, *not* the purported reason it is misleading, that governs whether it is forward-looking. *See* 15 U.S.C. § 78u-5 (defining forward-looking statements). Indeed, virtually every safe harbor case involves the allegation that a company's projections were false or misleading because the defendant was in possession of then-existing facts that cast doubt on them. "To accept [plaintiff's] position would be to discard a statutory framework that provides protection for forward-looking statements, replacing it instead with the notion that mere allegations of omission . . . would make such statements actionable." *In re Lockheed Martin Corp. Sec. Litig.*, 272 F. Supp. 2d 944, 950 (C.D. Cal. 2003).

Plaintiff also incorrectly asserts that it can evade the safe harbor if it alleges that a defendant had actual knowledge of a statement's falsity (a standard which, as shown above, it does not meet in any event). Opp. at 17. That position is flatly contradicted by the statutory language. The Reform Act provides that a person "***shall not be liable*** with respect to any

[6] For example, in connection with its revenue guidance on April 26, 2005, Connetics expressly stated: "If there is a delay in that timeline [for Velac approval] there will be an impact on our financial forecast . . . ." Ex. 1, at 10. Connetics provided similar cautionary statements in connection with its revenue guidance on April 14, 2005. Ex. 6, at 23 (2004 Form 10-K); Ex. 14 (identifying April 14, 2005 revenue guidance as forward-looking and incorporating 2004 Form 10-K). Notably, plaintiff does not dispute that (1) the safe harbor rule may apply to statements made in a Form 8-K filing and (2) the necessary cautionary language need not be contained in the same document as the disclosure, but can be incorporated by references to Form 10-K filings and other documents. *See* Def. Mem. at 20 n.20 & n.21.

forward-looking statement" if either (a) it was accompanied by "meaningful cautionary statements," "***or***" (b) "plaintiff fails to prove" actual knowledge of falsity. 15 U.S.C. § 78u-5(c)(1) (emphasis added). Thus, if (as here), the safe harbor applies, then the Court's inquiry is complete, regardless of any claims about defendants' alleged state of mind.[7]

B. Plaintiff Cannot State A Claim With Respect To Any Other Statement

1. Plaintiff Cannot State A Claim With Respect To Connetics' Statements Regarding The Phase III Clinical Trials

Regardless of whether Connetics' admittedly true statement in its 2004 Form 10-K regarding the excellent results of Velac's Phase III clinical trials could be construed as misleading in hindsight, plaintiff must nonetheless set forth facts establishing a cogent and compelling inference of scienter at the time the statement was made. Plaintiff's opposition makes no meaningful effort to meet that burden. To the contrary, plaintiff does not dispute that Connetics' 2004 Form 10-K merely repeated verbatim an earlier March 2004 press release that was not in any way misleading. Likewise, the facts show that defendants did not believe that the positive response in Tg.AC mice compromised the excellent results from the Phase III clinical trials in humans. That is especially true because of the lack of any negative comments by the FDA, the FDA's approval of other dermatological products that tested positive in animal carcinogenicity studies, the number of false positives associated with the Tg.AC mouse study, and the conclusion of the expert panel that Velac's test results were a false positive. As shown above, this Court has already recognized that the lack of any negative comments from the FDA and the FDA's approval of other dermatological products that tested positive in animal carcinogenicity studies refute any

[7] Plaintiff's interpretation ignores the statute's use of the disjunctive and would make the requirement for "meaningful cautionary statements" superfluous. *See Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253 (1992) (holding that "courts should disfavor interpretations of statutes that render language superfluous"). Other courts have rejected plaintiff's interpretation of the safe harbor and held that "if a statement is accompanied by 'meaningful cautionary language,' the defendants' state of mind is irrelevant." *Harris v. Ivax Corp.*, 182 F.3d 799, 803-04 (11th Cir. 1999); *see also In re Portal Software, Inc. Sec. Litig.*, 2006 WL 2385250, at *12 (N.D. Cal. Aug. 17, 2006) (same). The holding of *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920 (9th Cir. 2003), says nothing to the contrary. The discussion of the safe harbor in that case was dicta because it held that the statements at issue were not forward-looking. *Id.* at 936-37.

inference of scienter. Order at 14.

Plaintiff's only retort is to argue that although the Court properly considered these indisputable facts when analyzing "statements concerning FDA approval," the Court should nonetheless ignore the same facts when analyzing "statements concerning Velac's safety." Opp. at 19. Not surprisingly, plaintiff offers no support for this argument. Indeed, there is no principled basis to distinguish between defendants' state of mind when discussing Velac's Phase III clinical trial results and their state of mind when discussing Velac's prospects for approval by the FDA. *See Tellabs*, 127 S. Ct. at 2510 (requiring court to consider all relevant facts and "consider plausible nonculpable explanations for the defendant's conduct" when analyzing whether plaintiff has met its burden of pleading scienter). Moreover, by regulation, the FDA cannot approve a drug unless it determines that the drug is safe for its intended use and that its benefits outweigh its risks. 21 C.F.R. § 314.2. The fact that the FDA approved other dermatological products that tested positive in animal carcinogenicity studies that were less effective than Velac gave defendants ample grounds to believe that Velac was likewise safe.

Plaintiff also cannot distinguish the clear case law holding that a defendant's "rosy statements" about clinical trial results are not actionable even where certain preclinical animal tests show that the drug candidate is "dangerously toxic." *Vertex*, 357 F. Supp. 2d at 347, 352. As the court recognized in *Vertex*, "many drugs currently on the market are toxic depending on dosage levels and concentrations." *Id.* at 352. The same is true here. Many acne products that are less effective than Velac are carcinogenic in animal tests, but nonetheless are approved by the FDA for use by humans. For example, one of Velac's active ingredients – tretinoin – is a potential carcinogen based on animal laboratory studies, but nonetheless is widely prescribed for the treatment of acne. Ex. 36, at 2 (Retin-A label). Likewise, as shown above, benzoyl peroxide is widely used as an acne medication despite testing positive in Tg.AC mice and being a potential carcinogen. The fact that Velac tested positive in Tg.AC mice does not mean that defendants intended to mislead when they provided an undeniably accurate description of the statistically significant data from the Phase III clinical trials.

Plaintiff also has no answer for the numerous cases holding that a plaintiff cannot

establish scienter based on a defendant's alleged knowledge of inconclusive, albeit adverse test results. Those cases are particularly applicable here because plaintiff now alleges that the Tg.AC test results were inconclusive and that additional testing was necessary to determine if Velac was carcinogenic. *See, e.g., In re Carter-Wallace, Inc. Sec. Litig.*, 220 F.3d 36, 37-38, 40-42 (2d Cir. 2000) (holding that statements touting drug's "unprecedented safety profile" and lack of side effects were not intentionally misleading even though defendant failed to disclose "fifty-seven adverse medical reports"); *Borochoff v. GlaxoSmithKline*, 2008 WL 2073421, at *5-10 (S.D.N.Y. May 9, 2008) (holding that statements touting clinical data were not intentionally misleading even though defendant did not disclose inconclusive adverse data indicating that drug increased risk of heart attacks). In fact, courts have rejected claims based on positive statements regarding a drug's safety and efficacy even where – unlike here – the defendants were aware that the FDA had raised questions and concerns about the potentially adverse test data.[8] *See supra* n.3.

2. Plaintiff Cannot State A Claim With Respect To The Alleged Opinion Regarding Velac's Ability To Compete

Plaintiff's opposition never addresses the actual opinion regarding the strength of Velac's data. Rather, plaintiff simply excerpts that opinion – "one of the strongest data sets for an acne product" – from its context and then argues that it is a "factual question" as to how an investor would interpret the opinion. Opp. at 21-22. However, read in context, it is clear that the opinion was offered in direct response to a specific question about Velac's ***ability to compete***. *See* Ex. 2, at 17-18 ("[W]hat is your current understanding of the status of any potential competitors to Velac . . . [and] your internal plan for such a competitor?").[9] When the opinion is reviewed in

[8] In any event, putting aside plaintiff's failure to allege facts creating a strong inference of scienter, plaintiff has not established that Connetics' statements regarding the Phase III clinical results were in any way misleading. Connetics' statements were expressly limited to the data from the Phase III clinical trials. Plaintiff does not cite a single case holding that a defendant has a duty to disclose negative ***preclinical*** test results whenever it accurately describes positive ***clinical*** test results. In fact, the law is clear that there is no such duty to disclose preclinical test results particularly where, as here, those results are concededly inconclusive. *See GlaxoSmithKline*, 2008 WL 2073421, at *5 (holding that defendants had no duty to disclose meta-analysis results showing risk of heart attacks when they discussed other positive test results because meta-analysis results were inconclusive); *see also* Def. Mem. at 24 (cases cited therein).

[9] *See also* Ex. 2, at 3 ("our planning case is that ***there will be a competitive product for Velac*** but we have excellent data on Velac, we have now an expanded and very talented sales force, and we

total – as the law requires – there is only one reasonable inference. The speaker was offering an accurate and good faith opinion on the ability of Velac to compete against other products when and if it were approved. *See Osher v. JNI Corp.*, 308 F. Supp. 2d 1168, 1186 (S.D. Cal. 2004), *aff'd in relevant part*, 183 Fed. Appx. 604 (9th Cir. 2006) (holding court must consider statement in context, not just portion plaintiff "selectively quotes").

In any event, plaintiff has not alleged particularized facts demonstrating that defendants actually believed, or were deliberately reckless in not believing, that the Velac data was not "excellent" or that it was not "one of the strongest data sets for an acne product." To the contrary, the facts are undisputed that the Phase III clinical trial results were in fact excellent and demonstrated "a consistently robust and statistically superior treatment effect for Velac compared with clindamycin gel, tretinoin gel and placebo gel." Ex. 10 (Form 8-K). The Phase III clinical trial data demonstrated that Velac was significantly better and more effective than other acne medications that use only tretinoin or clindamycin, both of which are among the most commonly used active ingredients in acne medications. SAC ¶¶ 70, 72. Moreover, it is undisputed that the FDA never raised any concerns about any of the Velac data prior to April 13, 2005 and that many other acne products have been approved by the FDA despite testing positive in animal carcinogenicity studies. *See* Def. Mem. at 8-10.

Instead of setting forth particularized facts creating the necessary cogent and compelling inference of scienter, plaintiff attempts to shift the burden to defendants. *First*, plaintiff asserts that defendants' knowledge of other drugs that were approved despite testing positive in animal carcinogenicity studies "says nothing about . . . the percentage of drugs that test positive and the FDA rejects." Opp. at 23. However, plaintiff has identified ***no drug*** prior to Velac that was rejected by the FDA because it had a positive response in Tg.AC mice, much less such a drug that was brought to the attention of defendants. To the extent such drugs exist, plaintiff bears the burden of identifying the drugs and alleging particularized facts demonstrating that defendants were aware of them. Plaintiff makes no effort to do so.

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are [confident] that we will be successful in this market with our acne franchise and in particular with Velac") (emphasis added).

Second, plaintiff argues that defendants "proffer no evidence that the Tg.AC mouse study results in a 'high number' of false positives." Opp. at 23. However, once again, plaintiff cannot shift the burden to defendants. Rather, plaintiff bears the burden of pleading particularized facts demonstrating that defendants actually believed that the Tg.AC model reliably predicted risk to humans and that the FDA would not approve a drug that tested positive in the Tg.AC model without additional testing. Plaintiff has not met that burden. In fact, plaintiff acknowledged in its prior complaint that the Tg.AC model does not reliably predict risks to humans. Plaintiff cannot avoid that fact merely by deleting the previous allegation from its amended complaint and alleging that defendants have proffered no evidence on the point. *See* Def. Mem. at 8 n.7.

Third, plaintiff cannot meet its pleading burden by simply ignoring defendants' public statements that a panel of experts told defendants that Velac's positive response in the Tg.AC model was the result of a limitation in that model, *i.e.*, a false positive. SAC ¶¶ 117, 260, 263. Plaintiff does not allege any facts – much less facts with particularity – demonstrating that those statements were false. To the contrary, *Tellabs* holds that a court must consider inferences favorable to defendants, including the inference that defendants believed that the Tg.AC test results were a false positive. *Tellabs*, 127 S. Ct. at 2510.

Other courts have rejected securities fraud claims based on facts that are similar to those alleged by plaintiff. In *Neurocrine Biosciences*, for example, the plaintiff alleged that defendants misled the market when they said that they had "done the most comprehensive registration trial and program" for their drug candidate ("indiplon") and that they have "tracked other submissions that have gone to the [FDA] that we don't think are as robust as the indiplon data package . . ." 2008 WL 2053733, at *2. After the FDA denied the indiplon NDA because it lacked data on a key issue, plaintiff alleged that defendants knew that the indiplon data package was not "the most comprehensive" and most "robust." *Id.* Plaintiff alleged further that the company's V.P. of Regulatory Affairs and V.P. of Clinical Development allegedly told defendants that "there was insufficient data" with respect to the issue that resulted in the denial of approval. *Id.* The district court held that plaintiff had not pleaded particularized facts establishing a cogent and compelling inference of scienter because, as in this case, the FDA never questioned the sufficiency of the data

presented by defendants, publicly available FDA documents indicated that the data was adequate, and the alleged statements by the "confidential witnesses" lacked sufficient corroboration under the Reform Act.[10] *Id.* at *5-6.

3. Plaintiff Cannot State A Claim With Respect To The Form 8-K Or Any Other Statements On April 26, 2005

Plaintiff's opposition fails to address the fundamental deficiencies in its claim that Connetics intended to mislead shareholders when it voluntarily updated the market regarding the status of the Velac program on Form 8-K. That claim is based entirely on the uncorroborated allegation that "ECAC told Connetics" during an April 13, 2005 telephone call that the Tg.AC test results were a "serious issue." SAC ¶ 108. However, the only witness cited by plaintiff who was allegedly present for the call – CW 6 – does not state that defendants were present for the call, that ECAC characterized the test results as a "serious issue," or that anyone told defendants that ECAC characterized the test results as a "serious issue." *Id.* ¶ 43(f). Moreover, by plaintiff's own admission, CW 6 was not otherwise involved in the Velac program and therefore lacked knowledge about it. *Id.*

Instead of pleading particularized facts, plaintiff resorts to arguing that defendants must have been aware of the call – even though no defendant was even allegedly on it – given its importance and the alleged implementation of a trading ban after the call. Opp. at 29. However, the issue is not whether defendants were aware of a call during which ECAC disagreed with Connetics' interpretation of the Tg.AC test results. In fact, Connetics publicly disclosed such a call on April 26, 2005. Rather, the issue is whether plaintiff has pleaded particularized facts

[10] Moreover, the Ninth Circuit and other courts have also held that general expressions of optimism similar to those at issue here – for example, "solid," "extremely strong," "robust," "excellent results" – are not actionable under the securities laws. *See In re Vantive Corp. Sec. Litig.*, 283 F.3d 1079, 1087 (9th Cir. 2002) ("extremely strong"); *In re Impac Mortgage Holdings, Inc. Sec. Litig.*, 2008 WL 2104208, at *9-10 (C.D. Cal. May 19, 2008) ("solid"); *In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1076-77 (N.D. Cal. 2001) ("strong," "better than expected," "robust," "solid"); *In re Cornerstone Propane Partners, L.P. Sec. Litig.*, 355 F. Supp. 2d 1069, 1087 (N.D. Cal. 2005) ("excellent results"). That is true because such generalized expressions of optimism "are not capable of objective verification" and "lack a standard against which a reasonable investor could expect them to be pegged." *Impac Mortgage Holdings*, 2008 WL 2104208, at *10 (citations and internal quotations omitted).

demonstrating that ECAC characterized the Tg.AC test results as a "serious issue" and that defendants were expressly told of that characterization. It has not. *See In re Silicon Graphics Inc. Sec. Litig.*, 183 F.3d 970, 985 (9th Cir. 1999) (holding plaintiff must allege particularized facts demonstrating defendants were aware of alleged problems at the time the allegedly false statements were made); *Tripp v. Indymac Fin. Inc.*, 2007 WL 4591930, at *3 (C.D. Cal. Nov. 29, 2007) (same).

In any event, plaintiff has no answer for the fact that Connetics' decision to make a voluntary disclosure refutes any inference of scienter. It simply makes no sense that defendants intended to deceive the market by making a public disclosure that they were not obligated to make. If they wanted to deceive the market, they could have said nothing about the recent communication with the FDA. Plaintiff admits that it has no theory of scienter when it argues: "Whatever Defendants' motives, which Lead Plaintiff need not plead, the fact remains that Defendants told half-truths . . . ." Opp. at 27. Although plaintiff is not required to establish motive, it is required to plead a cogent and compelling theory of scienter. Here, plaintiff's failure to even articulate a theory of scienter is fatal to its claim.[11] *See Tellabs*, 127 S. Ct. at 2511 (holding "that omissions and ambiguities count against inferring scienter").

Plaintiff's claim is also refuted by the indisputable fact that neither ECAC nor the FDA told defendants that additional testing was necessary or that the Tg.AC study results were an insurmountable barrier to approval during the April 13, 2005 call. Plaintiff's arguments to the contrary simply misrepresent the allegations in the complaint.[12] Indeed, the FDA's regulations

[11] Plaintiff also has no answer for the fact that Connetics' decision to make the voluntary disclosure ***on Form 8-K*** refutes any inference of scienter. As shown in defendants' moving papers, the SEC's regulations are clear that Form 8-K disclosures are reserved for potentially "material changes" in an issuer's operations or events that the issuer "deems of importance to its security holders." Def. Mem. at 29. The facts show that defendants believed that they were disclosing a serious event to the market by making the disclosure on Form 8-K, an SEC filing that is reserved for important or material – *i.e.*, serious – events. Plaintiff does not argue otherwise.

[12] For instance, plaintiff argues that CW 6 "personally witnessed the ECAC tell Connetics that approval of Velac was not likely." Opp. at 29. The complaint alleges no such thing. SAC ¶ 43(f). At most, the complaint alleges that CW 6 formed an ***opinion*** after the call that was never communicated to anyone else. Moreover, the complaint acknowledges that CW 6 was not competent to form such an opinion since he/she had absolutely no experience with the Velac program prior to the call. *Id.*; *see also* Def. Mem. at 17 n.15; *Neurocrine Biosciences*, 2008 WL 2053733, at *6 ("Without specifics such as time and place, and the anonymous witness's basis for

state that ECAC's comments are advisory and "should not be interpreted by the sponsor as a measure of the approvability of their application." Def. Mem. at 29. Plaintiff misses the point when it argues: "*[d]efendants* posit no factual support . . . suggesting that the FDA regularly rejects the conclusions of [ECAC]." Opp. at 28 (emphasis added). The point is that *plaintiff* has pleaded no facts indicating that anybody told defendants that approval was unlikely, or that ECAC's statements – which are not to be interpreted as a measure of approvability – were supposed to be interpreted just the opposite way. Indeed, plaintiff has it backwards when it argues that "defendants posit no factual support." *Id.* Under *Tellabs*, plaintiff bears the burden of pleading facts establishing a strong inference of scienter.[13]

Plaintiff has also set forth no facts demonstrating that defendants' statements regarding benzoyl peroxide on April 26, 2005 were false or misleading, much less intentionally false or misleading. Far from pleading particularized facts, plaintiff attempts to evade its pleading burden by arguing that defendants "***offer no basis*** to believe that benzoyl peroxide/BenzClin resulted in a positive Tg.AC mouse test of the same significance as did Velac." Opp. at 28 (emphasis added). However, once again, plaintiff has it backwards. The law places the burden on plaintiff to plead particularized facts demonstrating not only that Velac's Tg.AC test results were not comparable to the test results for benzoyl peroxide and the many other dermal products that were approved by the FDA, but also that defendants ***knew*** they were not comparable. Plaintiff makes no effort to do so. Plaintiff's approach would turn *Tellabs* on its head and task every defendant with the burden of demonstrating the absence of fraud.[14]

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knowledge and involvement in the conversation, the Court cannot infer defendants secretly credited this warning despite their public expressions of confidence in the [New Drug] Application."); *In re Astrazeneca Sec. Litig.*, 2008 WL 2332325, at *17 (S.D.N.Y. June 3, 2008) ("As of the time when the FDA Advisory Committee met on September 10, AstraZeneca had its side of the case and the FDA had its side. . . . This does not mean . . . that the information issued publicly over the course of more than a year was dishonest or recklessly disseminated.").

[13] In any event, defendants have provided judicially noticeable facts showing that the FDA director has overruled the safety concerns of FDA advisors in the past. Def. Mem. at 11 n.11.

[14] Moreover, plaintiff cannot support its fraud claim with *arguments* about how Velac differs from other FDA approved drugs that tested positive in the Tg.AC model (*see, e.g.*, SAC ¶¶ 122-23), particularly where there is no allegation that any of those arguments was ever communicated to defendants. *See Lee v. Bender*, 2005 WL 1388968, at *7 (N.D. Cal. May 11, 2005) ("Plaintiff's opinions and legal arguments are not 'factual' allegations that may be considered by this Court."); *see also* Def. Mem. at 30 n.33 (collecting cases). Likewise, plaintiff's arguments

Plaintiff also has no explanation for its failure to set forth particularized facts demonstrating that the number of mice that allegedly tested positive ("89 out of 160") was somehow significant – such as, the *concentration levels* used, the *dosages* applied, and the *length of exposure* – much less that defendants understood that result to be significant. To the contrary, plaintiff's allegation that 56% of the mice tested positive draws entirely from a single sentence in the SEC's complaint (which was ***not*** filed against Connetics or any moving defendant), which in turn acknowledges that the Tg.AC study involved "varying formulations and dosages."[15] It is beyond dispute that "many drugs currently on the market are toxic depending on dosage levels and concentrations." *Vertex*, 357 F. Supp. 2d at 352. Without any factual detail about Velac's positive response in the Tg.AC study, there is no basis to draw any conclusions based on the alleged number of mice that tested positive.[16]

4. Plaintiff Cannot State A Claim With Respect To Statements Made To Third-Party Analysts

Plaintiff is wrong when it argues that it has stated a claim based on statements made to third-party analysts under the so-called "conduit theory" of liability.[17] Opp. at 24-25. To allege such a claim, plaintiff must allege that a specific defendant made a specific statement to an analyst, explain why the statement was false or misleading, and then plead facts establishing a cogent and compelling inference of scienter. *See Shuster v. Symmetricom, Inc.*, 1997 WL 269490, at *7 (N.D. Cal. Feb. 25, 1997) (dismissing claim based on analyst report where plaintiff failed to plead "specific statements . . . made by specific individuals and why such statements were false or misleading"); *In re Foundry Networks, Inc. Sec. Litig.*, 2002 WL 32354617, at *3 (N.D. Cal. June 6, 2002) (same); *Splash*, 2000 WL 1727377, at *18-19, 26-27 (same). Rather

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relating to Velac's vehicle are devoid of factual support and are inherently illogical. *See* Def. Mem. at 18 n.17.

[15] Declaration of Christopher J. Steskal In Support of Motion to Strike, Ex. 1 ¶ 17.

[16] *See Lipton v. Pathogenesis Corp.*, 284 F.3d 1027, 1036 (9th Cir. 2002) (dismissing claim based on internal report where plaintiff did not "plead, in any detail, the contents of . . . such report or the purported data"); *Silicon Graphics*,183 F.3d at 985 ("[Plaintiff] would have us speculate as to basis for the allegations about the reports, the severity of the problems, and the knowledge of the officers. We decline to do so.")

[17] Plaintiff concedes that it cannot state a claim under the so-called "entanglement theory" of liability. Opp. at 25.

than alleging such facts, plaintiff merely alleges that "defendants made favorable presentations concerning Velac" and then provides block quotes from a few analyst reports. SAC ¶¶ 255-58. However, none of the block quotes identifies an allegedly false statement by any defendant with the particularity required by the Reform Act, nor does plaintiff plead facts creating the necessary cogent and compelling inference of scienter.[18]

In any event, plaintiff cannot state a claim based on statements by analysts such as: "[t]he Company ***appeared enthusiastic***," "***[w]hile Connetics did not say so*** directly, ***it also appears to be confident*** in approval," and "[t]he takeaways . . . ***from our perspective*** are . . .". SAC ¶¶ 257-58 (emphasis added). These statements are not actionable because they do not purport to be a repeat of statements by defendants, nor do they even identify any defendant as providing the basis for the statements. In fact, the analyst reports are clear that "Connetics did not say" anything about Velac's prospects for approval. At most, the analyst reports cited by plaintiff merely "repackaged" defendants' actual statements in "vague and impressionistic terms." *In re LeapFrog Enters., Inc. Sec. Litig.*, 527 F. Supp. 2d 1033, 1051 (N.D. Cal. 2007). The law is clear that such statements are not actionable. *See id.* at 1051-52 (dismissing claim based on analyst statements such as "management was nonchalant" and "our recent meetings with management . . . enhanced our conviction . . ."); *In re Versant Object Tech. Corp.*, 2001 WL 34065027, at *8 (N.D. Cal. Dec. 4, 2001) (holding that analyst statements such as "meeting with Management confirms," "Management believes," and "Management indicated" are not actionable because they are not direct statements by defendants).[19]

[18] Plaintiff's repeated assertion that "management" told an analyst that "only one mouse" developed papillomas is legally deficient and absurd on its face. Opp. at 28. Not only does plaintiff fail to identify which defendant purportedly made the alleged statement, but plaintiff simply misreads the statement. The quoted section of the analyst report refers to one mouse *study* – *i.e.*, the Tg.AC study – not a single mouse. SAC ¶ 266.

[19] Plaintiff also cannot state a claim based on the Phase III clinical data referenced in an analyst report. *See* SAC ¶ 256 ("The company disclosed that both of its pivotal phase III trials achieved statistical significance (95% confidence level) on the primary endpoint of ISGA . . . on all three arms of the trial – vs. placebo, clindamycin and isotreinoin as single agent therapy."). Putting aside plaintiff's failure to allege that any of the defendants provided the referenced clinical data, plaintiff has failed to allege any facts establishing that any of the data was false or otherwise misleading, much less that it was provided to the analysts with the intent to deceive. In fact, this Court has already held that plaintiff cannot state a claim based on similar statements reporting the Phase III clinical trial results. Order at 12-13 n.3.

C. Plaintiff's Insider Trading Allegations Negate Any Inference Of Scienter

Plaintiff still has no answer for the fact that plaintiff's trading allegations actually refute any inference of scienter. *See* Opp. at 30. In fact, plaintiff now acknowledges that Dr. Krochmal could have – but did not – sell any shares during the class period. *Id*. Likewise, plaintiff does not dispute that Mr. Higgins actually ***acquired more shares*** of Connetics stock than he sold during the class period and the other defendants retained the vast majority of their shares. *See* Def. Mem. at 31. These facts alone devastate any inference of scienter. *See In re Glenayre Techs. Inc. Sec. Litig*., 1998 WL 915907, at *4 (S.D.N.Y. Dec. 30, 1998), *aff'd*, 201 F.3d 431 (2d Cir. 1999) ("one can assume that these high-ranking corporate officers, arguably the most knowledgeable . . . would be part of any fraudulent scheme to benefit from insider information through pre-emptive stock sales"); *In re Advanta Corp. Sec. Litig*., 180 F.3d 525, 540-541 (3d Cir. 1999) (no scienter where some defendants did not sell stock); *In re First Union Corp. Sec. Litig*., 128 F. Supp. 2d 871, 898-899 (W.D.N.C. 2001) (lack of trading refutes scienter).

III. PLAINTIFF'S OPPOSITION AGAIN FAILS TO SUPPORT A FRAUD CLAIM PERTAINING TO CONNETICS' FINANCIAL STATEMENTS

A. Plaintiff's Opposition Fails to Identify Any New Facts Showing That Connetics Deliberately Misstated Its Financial Results

As the Court has already held, it is well-established that the mere fact of a restatement does not give rise to an inference of scienter against any defendant. Order at 18; *DSAM Global Value Fund v. Altris Software, Inc.*, 288 F.3d 385, 390 (9th Cir. 2002); *In re Ramp Networks, Inc. Sec. Litig.*, 201 F. Supp. 2d 1051, 1065 (N.D. Cal. 2002). To establish a strong inference of scienter, plaintiff must make specific allegations of contemporaneous conditions known to each defendant that strongly suggest that the defendant understood that Connetics' accounting was incorrect at the time. *Vantive*, 283 F.3d at 1091; *Ramp*, 201 F. Supp. 2d at 1066. Rather than identifying such specific facts, plaintiff's opposition suffers from the same type of conclusory argument that it offered last time. For example, despite repeating its claim that there was a "massive" financial fraud at Connetics, plaintiff again never mentions the modest size of the restatement (a total of $1.1 million in adjustments in 2004, and $7.9 million in 2005) or reconciles its theory of fraud with the fact that, in some periods, the effect of the error was to *understate*

Connetics' reported results. Def. Mem. at 36. Nor does plaintiff come forward with specific facts establishing that anyone at Connetics intentionally or with deliberate recklessness misstated its reserves for chargebacks, rebates, or returns. *See id*. at 33-34.

In fact, the opposition barely references reserves at all. It never states what Connetics' reserves were in any period, who set them, what contemporaneous evidence existed establishing that the reserves in each period were inadequate and deliberately set too low, or whether or when defendants had such information or how they received it. Such necessary facts are completely absent, notwithstanding the Court's ruling that "to plead fraudulent intent based on GAAP violations, plaintiffs must allege facts showing that: (1) specific accounting decisions were improper; and (2) the defendants knew specific facts at the time that rendered their accounting determinations fraudulent." Order at 18 (citing *Morgan v. AXT, Inc.*, 2005 WL 2347125, at *14 (N.D. Cal. Sept. 23, 2005)).[20] Unable to address the Court's Order or the governing authorities, plaintiff simply ignores them.

Instead, plaintiff tries to side-step these requirements, asserting that such detail is unnecessary because the "accounting violations were too obvious to be mistakes" or because, like other companies, Connetics used "a sophisticated monitoring system" in an effort to track inventory in the distribution channel and help set reserves for chargebacks, rebates, and returns. Opp. at 34-36. Tellingly, however, plaintiff cites no case holding that there is an "obviousness" exception to the particularity requirements of the Reform Act (which would be rendered utterly meaningless by any such exception), much less how and why the mistakes in the reserve calculations here were known by or "obvious to" each defendant.[21] Neither of the two authorities

[20] *See also Vantive*, 283 F.3d at 1090-91 (dismissing claim where plaintiff failed to allege "specific contemporaneous conditions known to the defendants that would strongly suggest that the defendants understood that their recognition of revenues on 'millions of dollars of software' was 'excessive'"); *Mathews v. Centex Telemanagement, Inc.*, 1994 WL 269734, at *6 (N.D. Cal. June 8, 1994) (reserves are simply estimates of future events, and to plead fraud plaintiff must show they were deliberately derived in a manner inconsistent with reasonable accounting practices); *Kane v. Madge Networks N.V.*, 2000 WL 33208116, at *5-6 (N.D. Cal. May 26, 2000) (dismissing claim based on allegation that reserves were set too low), *aff'd sub nom.*, 32 Fed. Appx. 905 (9th Cir. 2002).

[21] To the contrary, the very disclosure which plaintiff cites negates the suggestion that the mistake was "obvious." Although plaintiff quotes Connetics' statement that it had calculated the reserve based on the original sales price rather than the price following any subsequent increases (Opp.

plaintiff cites support its "obviousness" theory. Indeed, in each of those cases, plaintiffs alleged specific facts to create a strong inference that senior management had knowledge of information "critical to a business' *core operations*." *See In re LDK Solar Sec. Litig.*, 2008 WL 2242185, at *15 (N.D. Cal. May 29, 2008) (emphasis added) (inferring knowledge based on, among other things, allegation that CFO received multiple detailed emails notifying him of accounting irregularities); *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 988 (9th Cir. 2008) (inferring knowledge where, *inter alia*, stop-work orders "halted tens of millions of dollars of the company's work" and management participated in negotiations with customer who issued stop-work order). Here, it can hardly be said that a reserve calculation is a "core business operation" of Connetics or that scienter can be inferred merely because a mistake was made.

Likewise, every company has internal controls or other systems designed to help it make reserve estimates. Plaintiff cites nothing suggesting that the existence of such a system is a guarantee of infallibility or gives rise to a strong inference of fraud whenever a mistake is made. That is precisely why this Court, like others, required plaintiff to come forward with concrete allegations that "'defendants knew specific facts at the time that rendered their accounting determinations fraudulent.'" Order at 18 (quoting *Morgan*, 2005 WL 2347125, at *14).[22] As the

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at 34), plaintiff ignores the disclosures in the same document indicating that there were other contributing factors, such as inaccurate and inconsistent inventory level reports provided by Connetics' three main wholesalers, and that Connetics had been estimating the reserve based on its cumulative historical return experience rather than the most recent three years data. Ex. 7, at 31, 43-44. Plaintiff makes no effort to explain how all of this was "obvious" to each defendant, much less explain how each defendant knew this error had been made. Because plaintiff cannot "selectively quote" documents to support a claim, *see, e.g., Osher*, 308 F. Supp. 2d at 1186, and because no cogent and compelling inference of scienter emerges "in light of other explanations" readily apparent in the same document on which plaintiff relies, plaintiff's claim fails. *Tellabs*, 127 S. Ct. at 2509-10 (courts must consider documents referenced in complaint in determining whether claim has been stated); *see Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002); *see also In re Applied Micro Circuits Corp. Sec. Litig.*, 2002 U.S. Dist. LEXIS 22403, at *12 (S.D. Cal. Oct. 3, 2002) (where plaintiff "refer[s] to the SEC filings in its amended complaint, [ ] it cannot therefore selectively argue that defendants cannot rely on the same material").

[22] Nor is plaintiff correct in repeating the same argument that scienter can be established merely by asserting that certifications made by Messrs. Wiggans and Higgins under the Sarbanes-Oxley Act were incorrect. *See Morgan*, 2005 WL 2347125, at *15 (certification fails to raise inference of scienter); *In re Invision Techs., Inc. Sec. Litig.*, 2006 WL 538752, at *7 n.3 (N.D. Cal. Jan. 24, 2006) (same). The case cited by plaintiff does not hold otherwise. *See In re Lattice Semiconductor Corp. Sec. Litig.*, 2006 WL 538756, at *17-18 (D. Or. Jan. 3, 2006) (Opp. at 41). Rather, in that case, it was the *contradiction* between the CFO's certification of effective internal controls and the company's admission that the very same CFO "overrode the internal controls to

Ninth Circuit has unequivocally held, "[t]he PSLRA requires a plaintiff to plead a complaint of securities fraud with an unprecedented degree of specificity and detail . . . . This is not an easy standard to comply with – it was not intended to be – and plaintiffs must be held to it." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003).[23]

B. Plaintiff's "Channel Stuffing" Arguments Are Equally Deficient

Nor can plaintiff rely on its woefully deficient "channel stuffing" allegations. Despite this Court's unequivocal Order requiring that channel stuffing be pleaded with particularity, plaintiff again fails to identify any specific instances where this occurred, the customer involved, the identity of the product, the "excess" amount that was supposedly returned, the amount that was improperly booked, or the basis for each defendants' knowledge of such facts. Order at 18-19 (citing *In re ICN Pharms., Inc. Sec. Litig.*, 299 F. Supp. 2d 1055, 1062 (C.D. Cal. 2004) and *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 204 (1st Cir. 1999)); *see also Splash*, 160 F. Supp. 2d at 1076; *Hockey v. Medhekar*, 30 F. Supp. 2d 1209, 1216 (N.D. Cal. 1998); *In re DDi Corp. Sec. Litig.*, 2005 U.S. Dist. LEXIS 1056, at *64 (C.D. Cal. Jan. 7, 2005). Plaintiff does not even mention, much less show it complied with, the Order or these cases. *See Vantive*, 283 F.3d at 1091 (complaint defective where "there is no sufficient allegation of the amounts by which revenues were allegedly overstated").

Instead of providing the specifics the Court and the case law require, plaintiff effectively seeks reconsideration, arguing in contravention of the Court's Order that "[t]here is no requirement that a complaint plead specific fraudulent transactions to allege accounting fraud" where plaintiff claims there is a generalized "faulty methodology." Opp. at 36-37. In making this argument, plaintiff ignores that Connetics actually *understated* its results in certain quarters (which eviscerates its entire theory), and again relies on the *same* allegations from so-called

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make incorrect and misleading journal entries" which bolstered an inference of scienter. *Id.* at *17. No such allegations exist here.

[23] The two authorities cited by plaintiff actually confirm that plaintiff may not plead in conclusory or general terms, but must allege with particularity sufficient details such as the products involved, the dates of the transactions, and the identities of the customers and employees involved in the transactions to support its allegations of fraud. *See In re Daou Sys., Inc. Sec. Litig.*, 411 F.3d 1006, 1016, 1019 (9th Cir. 2005); *In re Cabletron Sys., Inc.*, 311 F.3d 11, 30-31, 34 (1st Cir. 2002).

"confidential witnesses" who, as before, provide no specifics about transactions or accounting, but instead claim in one form or another that Connetics' management increased forecasts, were aggressive, or sought to sell product above historical prescription levels.[24] Because these are the same insufficient allegations as before, there is no reason for the Court to deviate from its prior ruling. *See* Order at 18-19; *In re Foundry Networks, Inc. Sec. Litig.*, 2003 WL 22077729, at *6 (N.D. Cal. Aug. 29, 2003) (allegations that defendants had "directed the sales and shipping departments to go ahead and ship product in September that customers had indicated should not . . . be shipped until the fourth quarter" insufficient to state channel stuffing claim); *In re Ashworth, Inc. Sec. Litig.*, 2000 WL 33176041, at *6 (S.D. Cal. July 18, 2000) (dismissing claim where complaint failed "to identify specific instances where [defendant] shipped product to a specified customer in a specified amount and booked that sale only to have that material returned at a later date").[25]

Because plaintiff lacks concrete facts that could give rise to a strong inference of scienter, the opposition ultimately again resorts to the predictable refrain that defendants "intentionally" shipped excess product in an effort to "meet financial projections." Opp. at 33. Such a generic allegation of motive is insufficient. *Lipton*, 284 F.3d at 1038. Moreover, whatever dubious merit such an argument might have in other cases, plaintiff makes no effort to show how it fits the facts

[24] As noted in defendants' prior motion, the fact that Connetics' forecasts or shipments exceeded historical prescription rates is hardly surprising since Connetics' business was growing. To meet such growth, management must necessarily predict the sales growth rate for each Connetics product, rather than rely on historical rates reflecting *past* sales. Accordingly, there is nothing fraudulent about management predicting future product sales that exceed historical prescription rates (even if so-called anonymous "witnesses" now claim to have disagreed with management's assessment). Plaintiff makes no effort to address this point. Likewise, plaintiff's assertion that unnamed defendants "falsified internal documents" (Opp. at 38-39) to justify shipments is pulled out of thin air and has no support anywhere in the SAC.

[25] Plaintiff's reliance on anonymous witnesses fails because plaintiff's allegations lack the *substantive* details needed to plead a channel stuffing or accounting fraud claim. *See* Def. Mem. at 37. In addition, plaintiff does not provide the job responsibilities of these witnesses, who are described with vague terms such as a "manager" of unidentified aspects of Connetics' business for as little as "six months" (SAC ¶¶ 43(h), (k) (CW8, 11)), as "sales" personnel (*id.* ¶¶ 43(c), 43(g)-(k) (CW3, 7-11)), or involved in "marketing" or "toxicology" (*id.* ¶¶ 43(a), (d) (CW1, 4)). Thus, there is still no allegation that any of these people had any involvement in or familiarity with the preparation of Connetics' financial statements, or any understanding of how Connetics was accounting for reserves or recognizing revenue. *See In re U.S. Aggregates, Inc. Sec. Litig.*, 235 F. Supp. 2d 1063, 1075 (N.D. Cal. 2002). Nor do they provide any facts identifying particular products, when the shipments occurred or any other specific details.

here. Indeed, plaintiff cannot do so given that (1) in three quarters, Connetics exceeded guidance even *after* the restatement (Q1 and Q2 of 2004, and Q3 of 2005); (2) in one quarter, Connetics did not meet guidance even *before* the restatement (Q4 of 2005); and (3) in two other quarters (Q2 of 2004 and Q2 of 2005), the effect of the restatement was to *increase*, not decrease, Connetics' net revenue (that is, Connetics' reported net revenue was *lower* than it should have been). *See* Def. Mem. at 36. Put simply, there is no pattern of making earnings that could support plaintiff's theory (based on a "flawed methodology" or otherwise), much less one that gives rise to a "cogent and compelling" inference of scienter. *Tellabs*, 127 S. Ct. at 2510.

C. Plaintiff's Loss Causation Argument Is Unavailing

As plaintiff concedes, Connetics announced that it would be restating its historical financial statements by approximately $8–9 million after the market closed on May 3, 2006. SAC ¶ 177. Because Connetics' stock price did not decrease, but instead increased, after that announcement, plaintiff cannot plead loss causation. *Dura Pharms. Inc. v. Broudo*, 544 U.S. 336, 342-43 (2005); *In re Impax Labs., Inc. Sec. Litig.*, 2007 WL 5076983, at *5 (N.D. Cal. Jan. 3, 2007); *see also* Def. Mem. at 37 (citing additional authorities). While plaintiff speculates in its opposition that information may have somehow "leaked" into the market earlier (Opp. at 43), plaintiff does not plead concrete facts to bolster that claim, such as the source of the "leak," to whom the information was disseminated, or how it became known on a market-wide basis. Indeed, plaintiff does not identify a single person, or reference a single analyst report or other document, even remotely suggesting there was such a "leak" or that the news announced on May 3 was somehow known sooner. In the absence of such facts, the price *increase* after May 3 eviscerates plaintiff's claim. *See Dura*, 544 U.S. at 347.[26]

[26] Plaintiff's attempt to show loss causation with respect to Connetics' July 10, 2006 announcement is equally unavailing. That announcement did not contain any new disclosure relating to Connetics' historical financial statements for 2004 and 2005, which are the subjects of plaintiff's supposed accounting claims. Rather, that announcement indicated that Connetics was revising its ***forward-looking guidance*** because it had made the business decision to "ship below estimated prescription demand during the remainder of 2006" in order to reduce "average wholesaler inventory levels to approximately two months on hand by the end of 2006." SAC ¶ 182. As the Supreme Court made clear in *Dura*, it is not enough for a disclosure to simply mention "inventory" or to "touch upon" the subject in some way – the disclosure must reveal the "relevant truth" to have "caused" the loss. 544 U.S. at 342-343. Plaintiff must be able to

IV. PLAINTIFF'S ARGUMENT UNDER SECTION 20A FAILS

As this Court previously held, plaintiff's Section 20A claim fails because plaintiff has "not satisfied the requirement that they show an independent violation of the Exchange Act." Order at 22. In any event, plaintiff concedes that there is no allegation of contemporaneous trading with Messrs. Wiggans and Vontz, but argues that allegations of contemporaneous trading with each defendant are not required. Opp. at 46. However, as this Court recognized, a person is only liable to an investor "who, 'contemporaneously with the purchase or sale of securities' by the insider, purchased or sold securities of the same class." Order at 21-22. Plaintiff cannot substitute a claim that one defendant traded contemporaneously with plaintiff for the requisite allegation that plaintiff traded contemporaneously with each individual defendant. *In re HI/FN, Inc. Sec. Litig*., 2000 WL 33775286, at *12 (N.D. Cal. Aug. 9, 2000) (liability for insider trading claims "is confined to persons who traded contemporaneously with the insider").

Plaintiff's argument that it need not allege contemporaneous trading with *each* defendant in order to have standing to assert a claim against that defendant on behalf of a putative class (Opp. at 45-46) is a nonstarter. As the court explicitly held in *In re Verifone Sec. Litig.*, 784 F. Supp. 1471, 1489 (N.D. Cal. 1992), *aff'd*, 11 F.3d 865 (9th Cir. 1993), where plaintiffs "cannot assert an individual claim against the defendants under § 20A," they may not "maintain a class action for the benefit of those who did trade contemporaneously with defendants." *See also In re Silicon Graphics Inc., Sec. Litig.* 970 F. Supp. 746, 761 (N.D. Cal. 1997) (dismissing § 20A

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distinguish the effect of the alleged misstatement from the "tangle of factors affecting price." *Id.* at 343. This is because the lower price of a stock "may reflect, not the earlier misrepresentation, but changed economic circumstances, changed investor expectations, industry-specific or firm-specific facts, conditions, or other events, which taken separately or together account for some or all of that lower price." *Id.* Indeed, since there was nothing about the historical restatement revealed on July 10, but only a change in forward-looking guidance, plaintiff cannot meet its burden to plead loss causation. *See Impax Labs.*, 2007 WL 5076983, at *4 (holding press releases regarding third quarter results insufficient to establish loss causation with respect to restatement of first and second quarter results); *In re Verisign, Inc., Deriv. Litig.*, 531 F. Supp. 2d 1173, 1208 (N.D. Cal. 2007) (holding that subsequent disclosure "is meaningless for purposes of showing loss causation" where the initial disclosure "constituted 'disclosure to the market'" and was followed by an increased stock price).

claim); *Buban v. O'Brien*, 1994 WL 324093, at *3 n.1 (N.D. Cal. June 22, 1994) (same).[27]

V. PLAINTIFF'S CONTROL PERSON ARGUMENT UNDER SECTION 20(A) FAILS

Since plaintiff fails to allege a viable Section 10(b) claim, plaintiff's allegations of control person liability against Messrs. Wiggans, Vontz and Higgins must be dismissed. *Paracor Fin., Inc. v. General Elec. Cap. Corp.*, 96 F.3d 1151, 1161 (9th Cir. 1996). The claim should also be dismissed because plaintiff does not even attempt to show that each defendant had "actual power" or "exerted" influence over the controlled person with respect to the specific transaction or activity upon which the primary violation was based. *See* Def. Mem. at 40; *Durham v. Kelly*, 810 F.2d 1500, 1503-04 (9th Cir. 1987). Plaintiff's failure to address the point in a 50 page brief is a concession it cannot do so.

VI. CONCLUSION

For the foregoing reasons, the Second Amended Complaint should be dismissed with prejudice.

Dated: July 18, 2008

FENWICK & WEST LLP

By: /s/ Christopher J. Steskal
Christopher J. Steskal

Attorneys for Defendants Connetics Corp., John L. Higgins, Lincoln Krochmal, C. Gregory Vontz, and Thomas G. Wiggans

[27] Nothing in the cases cited by plaintiff supports its contention that standing against all defendants is conferred simply by alleging a contemporaneous trade with a single defendant. To the contrary, in *Middlesex Ret. Sys. v. Quest Software Inc.*, 527 F. Supp. 2d 1164, 1196 (C.D. Cal. 2007), the court required plaintiff to amend its complaint to allege facts demonstrating that it traded contemporaneously with the defendant. Similarly, in *In re Cendant Corp. Litig.*, 60 F. Supp. 2d 354, 378-79 (D.N.J. 1999), the court held that plaintiffs met their burden of alleging they "traded contemporaneously with the insider" by providing "detailed schedules" demonstrating that they purchased stock on the same day the defendant sold stock. Finally, *In re Openwave Sys. Sec. Litig.*, 528 F. Supp. 2d 236, 256 n.12 (S.D.N.Y. 2007) is not controlling and is inconsistent with the Ninth Circuit's holding in *Neubronner v. Milken*, 6 F.3d 666, 670 (9th Cir. 1993) that plaintiff must specifically allege that contemporaneous trading occurred.